R2 ImageChecker®

Understanding R2 ImageChecker®

Software Versions 8.5–8.7

MAN-01049 Rev 001

HOLOGIC™

Screen-Film Mammography

Understanding R2 ImageChecker®

Software Versions 8.5–8.7

PN MAN-01049 Rev 001

HOLOGIC™

Technical Support

For support in North America contact:

Toll Free: +1 866.243.2533 (866.CHECKED)
Email: techsupport@r2tech.com
Hours: Monday – Friday, 6:00 AM – 5:00 PM, PT (GMT –8:00)
Website: **www.hologic.com**

For support in Europe, South America, or Asia, contact your local dealer or distributor.

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Hologic Inc.
35 Crosby Drive
Bedford, MA 01730-1401 USA
Tel: +1.781.999.7300
Sales: +1.781.999.7453
Fax: +1.781.280.0668

Hologic N.V.
Authorized Representative
Leuvensesteenweg 250A
1800 Vilvoorde, Belgium
Tel: +32.2.711.4680
Fax: +32.2.725.2087

Asia Pacific
Room 302, Hung Kei Building
5-8 Queen Victoria Street
Central, Hong Kong
Tel: +852.3102.9200

MergeCOM-3 Advanced Integrator's Tool Kit is a product of Merge Healthcare.

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Part 1: Introduction

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R2 ImageChecker® is a software application used for analyzing mammography images. This manual describes R2 ImageChecker software versions 8.5, 8.6, and 8.7, which were developed to provide the ImageChecker software as a licensed option with these Hologic film scanning systems:

- R2 DMax System
- R2 LS System
- R2 DM System

These systems support a second application, R2 DigitalNow™, which the systems use to create archivable digital mammography image files from the original films.

R2 ImageChecker 8.7 is available as a software upgrade for customers that have previous versions. For customers using full-field digital mammography (FFDM) systems, the ImageChecker software is also available as a licensed option with Hologic's R2 Cenova digital mammography server. For more information, contact your Hologic customer representative.

The information in this manual is intended to serve as a reference for radiologists and clinic personnel who need to understand how ImageChecker computer-aided detection (CAD) can be integrated into their practice.

1.1. Intended Use

ImageChecker is a software application intended to identify and mark regions of interest on routine screening and diagnostic mammograms to bring them to the attention of the radiologist after the initial reading has been completed. ImageChecker assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

1.2. Resources Available

In addition to this manual, the following resources are available to assist you:

- **R2 Member Center:** This website provides quick access to electronic (pdf) versions of Hologic manuals and training materials. You can find the R2 Member Center by visiting the Hologic website (www.hologic.com). See the R2U flyer that accompanies this product for instructions on accessing the R2 Member Center.
- **Manuals:** The manuals for the R2 film scanning systems are listed below:

  – *Understanding R2 ImageChecker*

  – *R2 DMax User Manual*

  – *R2 DM User Manual*

  – *R2 LS User Manual*

  – *R2 DMax/DM/DX/LS Service Manual*

  – *R2 DMax/DM/DX/LS Release Notes*

  – *R2 DMax/DM/DX/LS DICOM Conformance Statement*

  You can obtain additional copies of printed manuals through your Hologic Account Manager. The DICOM Conformance Statement is available at www.hologic.com.
- **Training:** The Hologic Applications team is available to train your staff, should you feel they need additional training. To purchase additional personalized instruction, contact your Hologic Account Manager.
- **Technical Support and Service:** For support in North America contact:

  Toll Free: +1.866.243.2533 (+1.866.CHECKED)

  Email: r2support@hologic.com

  Hours: Monday – Friday, 6:00 AM – 5:00 PM, PT (GMT –8:00)

  Website: www.hologic.com

  For support in Europe, South America, or Asia, contact your local dealer or distributor.

1.3. Warnings and Precautions

⚠ ***Note:*** *For Warnings and Cautions related to the installation, operation, and maintenance of the R2 film scanning system, refer to the user manual accompanying the product.*

- The radiologist should base interpretation only on original diagnostic-quality images and not depend on ImageChecker CAD marks for interpretation.
- The device is a detection aid, not an interpretative aid. ImageChecker CAD marks should be activated only after the first reading.
- The device does not enhance what the user sees; rather it helps to identify regions on mammograms that should be re-examined.
- The ImageChecker software marks calcification features with triangles (Calc marks) and mass features with asterisks (Mass marks). The software marks mass and calcification features that occur at the same location on the image with pointed crosses (Malc marks). These features may not represent cancer, and the skill of the user is still required for proper interpretation of the marked areas.
- EmphaSize (variable-size) marks – Sites may choose to display prominence detail, in which case the size of a Calc, Mass, or Malc mark is proportional to the ranking of the feature by the algorithm. The marked features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- For proper system operation, the technical quality of the original films or images (e.g., contrast) should meet relevant MQSA standards (or the appropriate national standards) and be acceptable to the mammographer.
- The use of digitized images (scanned film images) for primary reading has not been approved by MQSA. Digitized film images retrieved from archive should be used only for the purpose of comparison with digital images meeting the current standard.
- During routine interpretation of mammograms and results produced by ImageChecker CAD, Hologic recommends use of a mammography workstation that has been FDA-approved, recently calibrated, and employs a CAD marking schema authorized by Hologic.
- ImageChecker software does not identify all areas that are suspicious for cancer.

  – The software does not mark all lesions and a user should not be dissuaded from working up a finding if the software fails to mark that site.

  – The software is not designed to detect changes from prior mammograms.

  – The software is not designed to detect skin thickening or nipple retractions.

  – Conditions of the breast that diminish mammographic sensitivity, such as density of normal tissue, also diminish the sensitivity of the software.

  – The software is more sensitive for detection of calcifications than masses, and the sensitivity depends on the site-specific operating points chosen. For sensitivity values, see '**3.8. CAD Operating Points**'. In addition to not marking all masses, the algorithm has a lower sensitivity for masses greater than 2.5 cm in diameter.

– Individual practice patterns may influence results obtained when using ImageChecker CAD. Therefore, each facility and radiologist should carefully monitor the results that the software has on their practice of mammography in order to optimize its effectiveness.

- The performance of the system has *not* been characterized for mammograms from patients with:

  – Breast implants. Process only Implant-Displaced Views with less than 2.5 cm (1 in) of the breast implant appearing on the image.

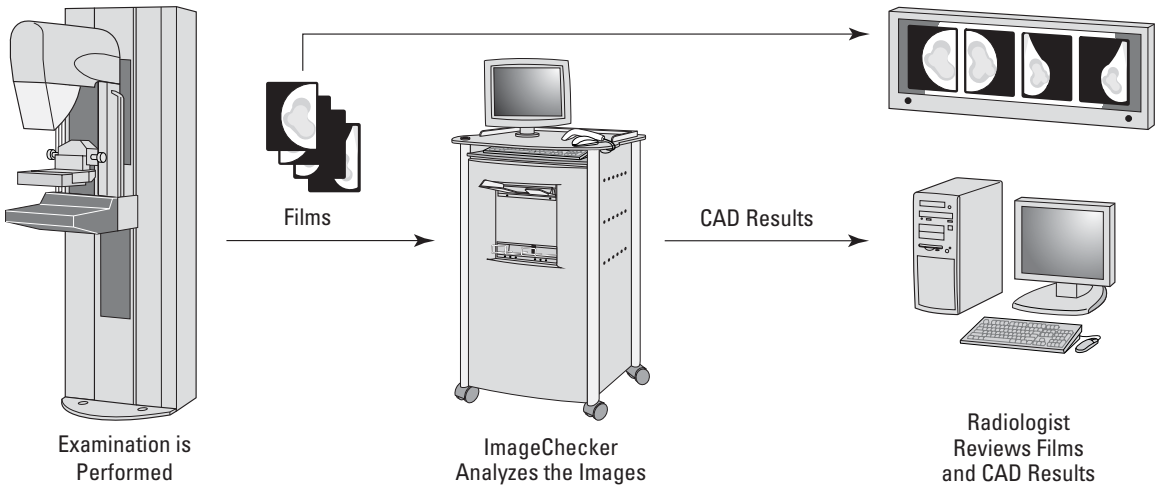
  – Special diagnostic views (e.g., magnified views or spot-compressed views). Process only full-view diagnostic images.

  – Segmented views of the breast (e.g., 'mosaic' views) with no clear breast border. Process only views with breast borders.

1.4. Overview of ImageChecker CAD

Systems configured with R2 ImageChecker 8.5–8.7 analyze digitized film mammography images with a software algorithm that identifies regions of interest, which can include clusters of bright spots (suggestive of calcification clusters), and dense regions with or without radiating lines (suggestive of masses or architectural distortions). The systems generate results that include ImageChecker CAD marks identifying the regions of interest. The results produced are either image files, Mammography CAD SR (Structured Report) objects, or both.

After making an initial interpretation from the original mammograms, the radiologist displays the ImageChecker results and chooses whether or not to reinspect the marked regions on the original mammogram. The ImageChecker algorithm marks visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications or masses. The marked areas may be something other than an actual abnormality, which the radiologist generally recognizes upon a second review of the original mammogram.



ImageChecker Workflow

1.5. Benefits of ImageChecker CAD

The interpretation of mammograms is challenging. Normal breast tissue varies widely among women, even for the same woman over time or at different times of the month. The radiologist also has to balance the need for accurate detection of breast cancer with the need to limit the number of unnecessary procedures. The combination of viewing a large number of cases, radiologist fatigue, the complex image of the breast structure, and the subtle nature of certain observable characteristics of the disease can result in false-negative readings. In fact, studies show that half of undetected cancers are missed due to observational oversights. The prevalence of observational oversights is not strongly related to experience and may be inevitable with human observers.

R2 ImageChecker functions like a spellchecker for medical images. It is designed to help radiologists in reducing the number of false-negative readings due to observational oversight by drawing their attention to areas that may warrant a second review. Use of ImageChecker CAD can result in earlier detection of up to 23.4% of the cancers currently detected with screening mammography in those women who had a prior screening mammogram 9–24 months earlier. Early detection is the key to higher survival rates, better prognosis, and lower treatment costs.

1.6. Devices Used with ImageChecker CAD

All systems with R2 ImageChecker 8.5–8.7 include a film scanner for scanning mammography X-ray films and a processing unit computer configured with the R2 image-processing software. There are three models:

- R2 DMax System
- R2 LS System
- R2 DM System

Facilities must also have an output device in order to review or store the CAD results. These devices may include any of the following:

- R2 CheckMate Ultra™ display unit
- Postscript printer
- Diagnostic mammography review workstation (such as Hologic's SecurView$_{DX}$)
- PACS (Picture Archiving and Communication System)

The system devices are connected by a computer network and can be in the same room, different rooms, the same building, different buildings, or even different cities. The R2 processing unit can send results to several different output devices.

The R2 DMax, LS, and DM systems are designed to:

- Scan mammography X-ray films and convert them into digital image files
- Allow users to review the scanned images, and to reorient, label, and reprocess the images as needed.
- Analyze the images using the R2 ImageChecker algorithm to detect regions of interest.
- Transmit the study results so they can be viewed on an output device such as the R2 CheckMate Ultra display unit, printer, diagnostic review workstation (or to a PACS for archiving).

1.7. ImageChecker Features

R2 ImageChecker provides the following features, which are discussed below:

- **RightOn CAD Marks**
- **EmphaSize**
- **PeerView and PeerView Digital**
- **Operating Points**

Upon installation, the Hologic field service engineer will configure the software based on the preferences of site personnel. Thereafter, your Hologic representative can help you add a new license (such as DigitalNow) and enable or disable features as needed.

For more information on ImageChecker features, see '**Part 3: Algorithm Description**'.

⚠ ***Important!*** *Display of results from each ImageChecker feature depends upon several factors, in particular:*

- *The feature must be licensed and enabled on the R2 processing unit.*
- *The review workstation must be equipped with software that can interpret the output produced by the processing unit.*

Some workstations can interpret only a subset of ImageChecker features. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.

RightOn CAD Marks

The ImageChecker software provides three types of RightOn™ CAD marks (Mass, Calc, and Malc) that can appear in the results. You can choose to display any or all of the three types of marks. Each mark identifies a region of interest for the radiologist to review.

Calc – Marks regions suggestive of calcifications.

Mass – Marks regions suggestive of masses or architectural distortions.

Malc – Marks regions where Calc and Mass marks are coincident.

EmphaSize

The processing unit is configured by default to convert the CAD marks to EmphaSize™ marks, which can be viewed on some diagnostic review workstations, as well as the R2 output devices (R2 CheckMate Ultra and postscript printer). EmphaSize produces CAD marks of variable size that correlate to feature significance. When the algorithm determines that a region is more significant, the CAD mark appears larger, indicating that the region should receive more emphasis from the radiologist. EmphaSize marks can be disabled if clinic staff choose not to use them. For more information see '**3.3. EmphaSize Marks**'.

PeerView and PeerView Digital

PeerView™ and PeerView Digital are optional features that help radiologists better understand why a region of interest was marked. PeerView and PeerView Digital

display a close-up, high-resolution section of the image and highlight physical features found by the algorithm, facilitating the radiologist's reassessment of the mammograms.

- PeerView is licensed on CheckMate Ultra display units and Mammolux motorized viewers. When licensed, PeerView asks the R2 DMax system to send the additional high-resolution CAD information to the display unit.
- PeerView Digital is licensed on the DMax system. When licensed, PeerView Digital creates extra CAD information in the Mammography CAD SR output, viewable on some softcopy review workstations. It displays a close-up, high-resolution section of the image, highlights physical features found by the algorithm, and produces measurements of the physical features.

For more information see '3.4. PeerView and PeerView Digital'.

Operating Points

The ImageChecker algorithm offers three operating points (i.e., CAD algorithm thresholds) to accommodate differing radiologist preferences: operating point 0, which emphasizes specificity (a low false-mark rate), operating point 1, which is a balanced intermediate point, and operating point 2, which emphasizes sensitivity. The algorithm performance for each of the operating points is summarized below:

Operating Point	0	1	2
Calcification Sensitivity	95%	96%	97%
Mass Sensitivity	83%	88%	90%
False Marks per Case	1.0	1.5	2.0

When your system is installed, the R2 processing unit is configured to use operating point 1 for masses and operating point 2 for calcifications. You can choose other settings, or your service representative can change the operating points at a later time. For new customers, Hologic recommends using the default settings for the first four to six weeks to allow you to become familiar with the R2 marks and algorithm behavior.

The ImageChecker algorithm provides the medical-imaging industry's highest sensitivity at any given false-mark rate. ImageChecker was the first computer-aided detection software approved by the FDA for full-view diagnostic and screening mammograms. Since that first approval, the ImageChecker software has been refined many times, resulting in an algorithm that is highly sensitive with few false marks. For more information, see '3.8. CAD Operating Points'.

Part 2: Data Inputs and Outputs

- 2.1. Film-Based CAD with DigitalNow
- 2.2. CAD Inputs and Supported Views
- 2.3. Image and Case Processing
- 2.4. System Outputs

Part 2 explains how information flows through systems with ImageChecker CAD, the supported mammography views, and the result formats.

ImageChecker 8.5–8.7 runs on Hologic's film-scan systems (R2 DMax, DX, DM, and LS). Facilities can also run ImageChecker on images produced by full-field digital mammography (FFDM) systems such as Hologic's Selenia. Digital CAD requires a different processing computer, the R2 Cenova server, and a different ImageChecker version (9.0 or greater). For further information, see the corresponding manual, *Understanding ImageChecker*, for the appropriate software version (9.0 or greater).

2.1. Film-Based CAD with DigitalNow

With the R2 DMax, DM, DX, and LS systems, scanned X-ray films can be analyzed using ImageChecker CAD, or they can be converted to archivable digital images using R2 DigitalNow. The flow of data through the systems is as follows (see diagram on the next page).

Films

Film priors are fed into the processing unit with film scanner, which scans (digitizes) the films and processes the resulting images.

⚠ ***Note:*** *Every time films are rescanned, the image created is subtly different. This difference is of no consequence to a human observer, but slight rotation, shift, and electronic noise differences will cause some CAD marks to vary with each rescan. This behavior is expected. Also, CAD marks may vary if the ImageChecker software has been upgraded to a newer revision since the mammography films were first processed.*

Processing Unit with Film Scanner

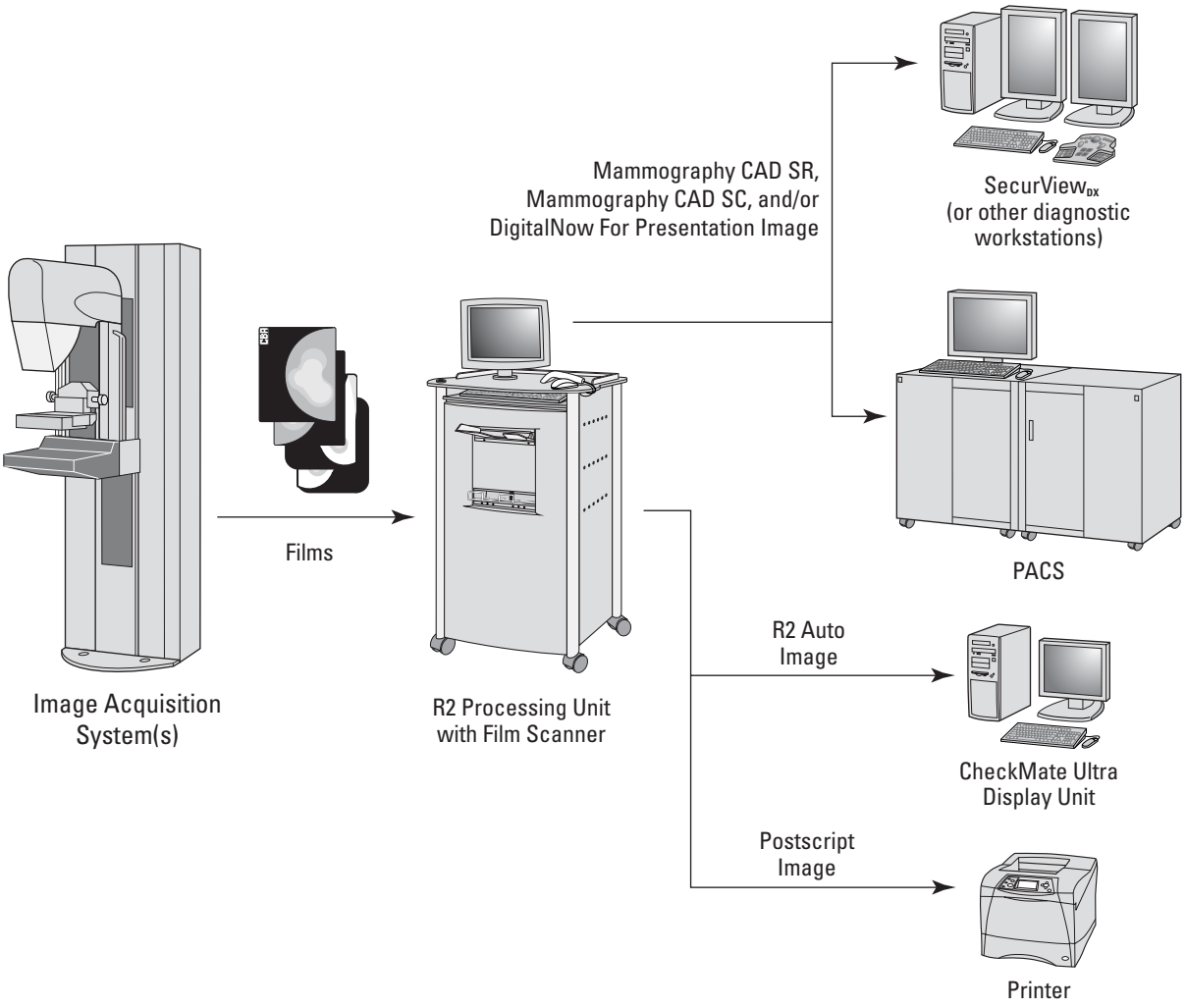
The R2 processing unit with film scanner is used to scan and digitize the films, analyze the images using ImageChecker, and then send the resulting images and/or CAD output to a review workstation, PACS, or printer.

Patient Database Connectivity

When scanning films for digital archiving, sites need the ability to retrieve patient information in order to add the required identification information to the resulting Digital Mammography X-Ray images. Sites can retrieve patient data by querying a PACS or RIS (Radiology Information System). As an alternative, sites can enter patient data manually by using the R2 Patient ID feature.

Diagnostic Review Workstation, PACS and Printer

Users can review or archive the results on a variety of devices. The form of the results depends upon the capabilities of the output device.

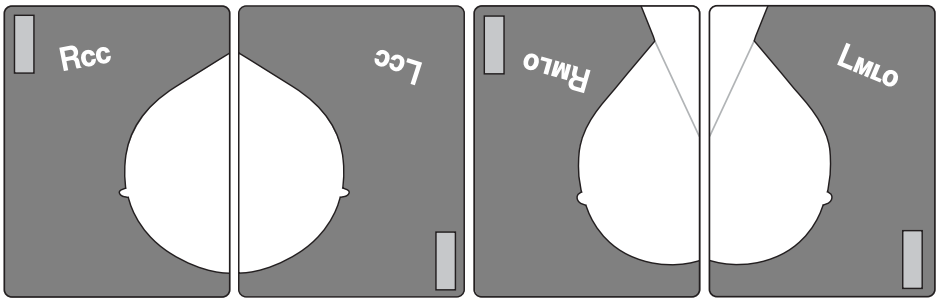


ImageChecker and DigitalNow

2.2. CAD Inputs and Supported Views

If your system has the ImageChecker license, all images are CAD-processed if the views are supported by the software. The four 'standard views' processed automatically by the ImageChecker software are:

- RCC – Right Cranio-Caudal
- LCC – Left Cranio-Caudal
- RMLO – Right Medio-Lateral Oblique
- LMLO – Left Medio-Lateral Oblique



The Four Standard Views

The following table lists the views supported by the ImageChecker software:

ImageChecker Supported Views and View Modifiers		ACR MQCM* View Label
Screening Views	Cranio-Caudal	CC
	Medio-Lateral Oblique	MLO
Equivalent Views	Medio-Lateral	ML
	Cranio-Caudal Exaggerated	XCC
	Cranio-Caudal Exaggerated Laterally	XCCL
	Cranio-Caudal Exaggerated Medially	XCCM
Reversed Equivalent Views**	Latero-Medial	LM
	Latero-Medial Oblique	LMO
	Cranial-Caudal From Below	FB
	Superolateral to Inferomedial Oblique	SIO

*American College of Radiology Mammography Quality Control Manual 1999

**CAD results for Reversed Equivalent views are supported with the Mammography CAD SR format only. These views are not supported with the Mammography CAD SC format, on the R2 CheckMate Ultra display unit, or on the postscript printout.

View Modifiers

View modifiers can be added to describe any supported view. However, some modifiers are not supported for CAD processing. Using a non-supported modifier will prevent CAD processing a supported view. The following table lists the DICOM view modifiers and indicates which are supported for CAD processing.

View Modifier	Label	View Modified	CAD Support
Axillary Tail	AT	MLO	●
Cleavage	CV	CC	
Implant Displaced*	ID	Any	●
Implant Present	(none)	Any	
Magnification	M…	Any	
Partial View	(none)	Any	
Rolled Lateral	…RL	Any	●
Rolled Medial	…RM	Any	●
Rolled Inferior	…RI	Any	●
Rolled Superior	…RS	Any	●
Spot Compression	S	Any	
Tangential	TAN	Any	●

* Implant-displaced views with a maximum of 2.5 cm (1 in) of implant imaged.

Images with Breast Implants

The ImageChecker software does attempt to process images with breast implants. For images with breast implants, send only Implant Displaced views to the system. Images with more than 2.5 cm (1 in) of the breast implant appearing on the image may not be processed correctly.

⚠ ***Note:*** *The Implant Present and Partial View modifier labels are NOT added to the view description, but are present in the DICOM header of the DigitalNow image.*

2.3. Image and Case Processing

During processing, the ImageChecker software analyzes each received image, as long as the view is supported by the software. The algorithm searches for patterns suggestive of calcification clusters and masses or architectural distortions, characterizes each suspected lesion, and finally determines the location and numbers of CAD marks for the image. This initial analysis is known as *image processing*.

The R2 processing unit groups successive images from a single patient into a study, with up to 24 images per study. For most patients, a study consists of the four screening views:

- RCC – Right Cranio-Caudal
- LCC – Left Cranio-Caudal
- RMLO – Right Medio-Lateral Oblique
- LMLO – Left Medio-Lateral Oblique

As an additional step when a study includes two or more views, the ImageChecker algorithm selects up to four views and compares the images to each other in a process known as *case processing*. By checking for similarities and differences between the images, the algorithm can further refine its findings for the four selected views. When case processing is complete, the ImageChecker provides results for both the case processing images and the remaining images.

As a result of the case processing analyses, ImageChecker may produce a different set of CAD marks for an individual image than when the image is part of a case. When ImageChecker applies the more sophisticated case processing rules it may add or discard marks. For example:

- Some large masses are marked only when the image is part of the bilateral asymmetry analysis used for case processing.
- Some marks may be discarded when the image is subjected to the mark capping limitations used for case processing. For more information, see '**Limiting the Number of Marks**' in '**3.2. RightOn CAD Marks**'.

For more information about image and case processing, see '**3.6. Detecting Calcifications**' and '**3.7. Detecting Masses**'.

Selecting Images for Case Processing

The ImageChecker algorithm uses the following criteria to determine which images will be case-processed:

- If a study includes one image for each of the four screening views or their equivalents, then all images are case-processed.
- When a study includes multiple images of the same view and laterality (e.g., two RCC views), case processing is performed on the *last* scanned film for each of the four screening views or their equivalents. (Refer to the diagram on the following page.)
- If a study does not include one or more of the four screening views, then the equivalent views (or the reversed equivalent views) are case-processed, if they are present. Screening views are given preference over equivalent views, which in turn are given preference over reversed equivalent views.
- The view modifiers, if present, do not affect which images are selected for case processing.
- When a study includes multiple equivalent (or reversed equivalent) views, the views selected for case processing are based on the following preference order:

Preference Order	CC Equivalent	MLO Equivalent
1	CC	MLO
2	FB*	ML
3	XCC	LM*
4	XCCL	LMO*
5	XCCM	SIO*

*Indicates a reversed view, not available for display units, printouts, or CAD SC output.

For example, if a study includes the four screening views plus two additional RMLO images (as is shown in the figure below), all the images are image-processed separately. However, when selecting images for case processing, the ImageChecker algorithm includes only the *last* RMLO image acquired by the scanner (along with the other three screening views). As is shown below, the algorithm would select the RMLO 3 image for case processing.

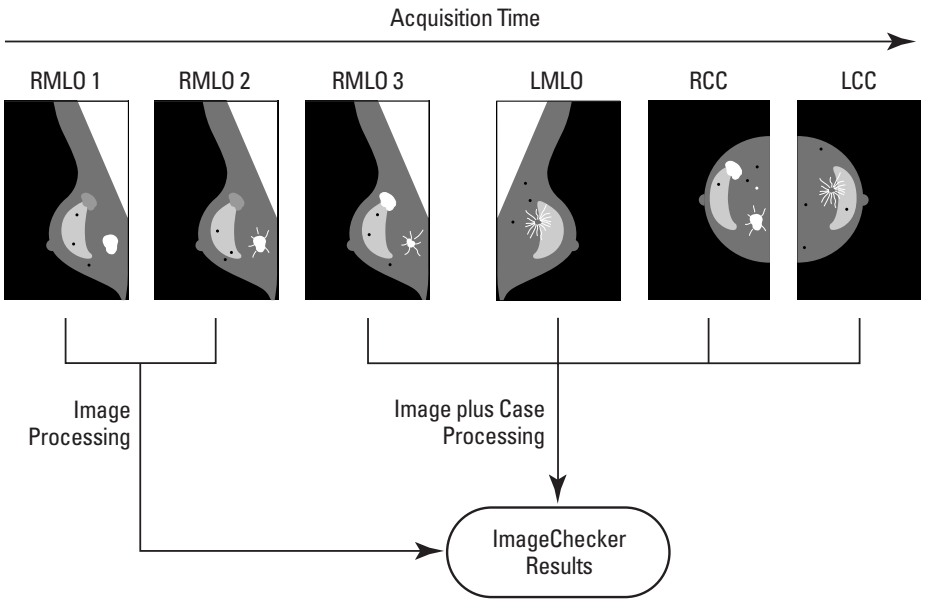


Image and Case Processing

As a further example, for a study with segmented breast views including multiple CC images, you may choose to image the anterior (ductal) region of the breast last in the sequence to ensure that that image is case-processed.

2.4. System Outputs

The R2 processing unit can be configured to send results in one or more of the following formats:

- **R2 Auto** is the format used to display the four screening views with CAD results on a CheckMate Ultra display unit or Mammolux motorized viewer. With this format, the CAD results appear over a montage of low-resolution images. Normally, the four screening views appear, although it is also possible to produce CAD results from films that show Equivalent Views.
- **Mammography CAD SC** is a Secondary Capture image that provides the same low-resolution images and CAD results as appear in the R2 Auto format. This format is useful for PACS that do not support CAD SR.
- **Postscript** files, suitable for printing on a postscript printer, provide the same low-resolution images and CAD results as appear in the R2 Auto format. For an example, see the **CAD results report** on page **19**.
- **Mammography CAD SR 8.x** results are derived from the latest version of the ImageChecker algorithm. This is the DICOM standard format for CAD results. Mammography CAD SR objects are generally useful only when viewed with the images on an advanced diagnostic review workstation.
- **Mammography CAD SR 5.x** provides backward compatibility with previous releases of ImageChecker 5.x products. The 5.x format provides RightOn Calc and Mass marks but not EmphaSize or PeerView.
- **DigitalNow** is a traditional DICOM Digital Mammography X-Ray For Presentation image where the image is comprised of Natural Pixel Values, the values actually created by the film scanner. These can be created as 50- or 100-micron image files. DigitalNow images do not include CAD results.

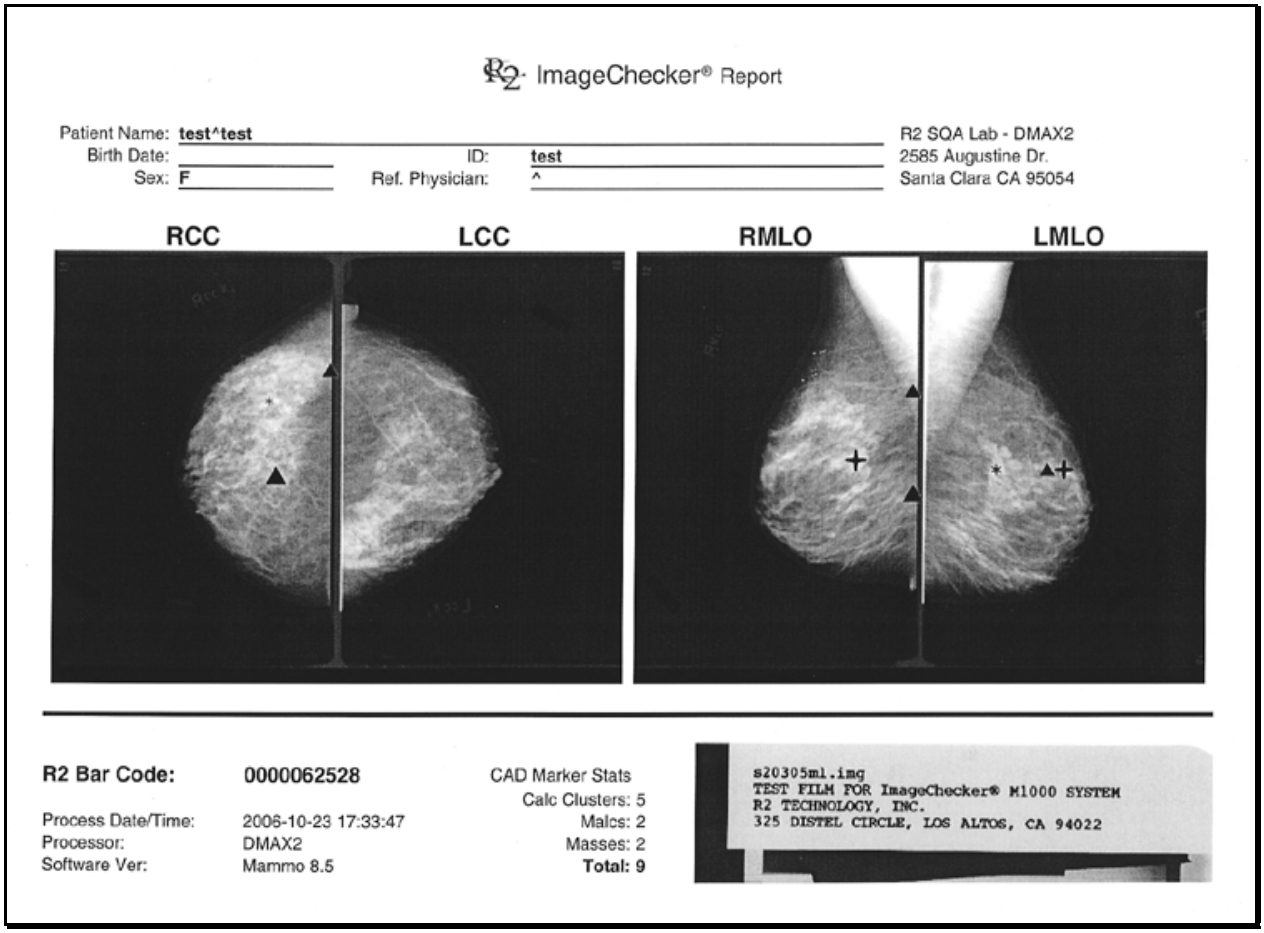
⚠ ***Note:*** *CAD results for Reversed Equivalent views are supported with the Mammography CAD SR format only. These views are not supported with the Mammography CAD SC format, the R2 Auto format, or the postscript printout.*

The Mammography CAD SR format is the DICOM standard format for CAD results. For more information, refer to the *R2 DMax/DX/DM/LS DICOM Conformance Statement*.

If the results are not archived, they can be recreated at a later time if the films are still available. In most cases, the same ImageChecker results should be generated each time the images are reprocessed.

CAD Results Report

If the Hologic service engineer has configured the system to print CAD results, the results are automatically printed when processing is complete. The following is an example of a printed CAD results report:



Part 3: Algorithm Description

- 3.1. ImageChecker CAD Algorithm
- 3.2. RightOn CAD Marks
- 3.3. EmphaSize Marks
- 3.4. PeerView and PeerView Digital
- 3.5. What the Algorithm Detects
- 3.6. Detecting Calcifications
- 3.7. Detecting Masses
- 3.8. CAD Operating Points

Part 3 describes the algorithm used by the ImageChecker software when analyzing mammography images.

3.1. ImageChecker CAD Algorithm

R2 Technology's ImageChecker algorithm looks for characteristics commonly associated with cancer – specifically, calcifications and masses (including architectural distortions). The algorithm ranks its findings by likelihood, places marks on those regions above a fixed threshold of likelihood (operating point), and then sends the results to the review workstation.

ImageChecker provides the medical-imaging industry's highest sensitivity at any given false-mark rate. The algorithm offers three operating points to accommodate differing radiologist preferences. For more information, see '3.8. CAD Operating Points'.

3.2. RightOn CAD Marks

ImageChecker provides three types of CAD marks. Each RightOn™ mark indicates a region of interest for the radiologist to review. There are two basic types of marks plus one composite mark, as summarized below.

Calc – Marks regions suggestive of calcifications.

Mass – Marks regions suggestive of masses or architectural distortions.

Malc – Marks regions where Calc and Mass marks are coincident.

ImageChecker CAD Marks

⚠ ***Note:*** *Not all mammography workstations can display Malc marks. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

Limiting the Number of Marks

The software limits or 'caps' the number of CAD marks for each image and case. The actual number of CAD marks produced depends upon the individual case and the operating point selected for the CAD algorithm.

Views	Per Image Limit	Per Case Limit
Screening views (RCC, LCC, RMLO, LMLO)	3 Calc marks 2 Mass marks 2 Malc marks	8 Calc marks 4 Mass marks 4 Malc marks
Extra views	3 Calc marks 2 Mass marks 2 Malc marks	Dependent upon the number of images*

*For cases with more than four views, the maximum number of marks per case depends upon the number of images in the case.

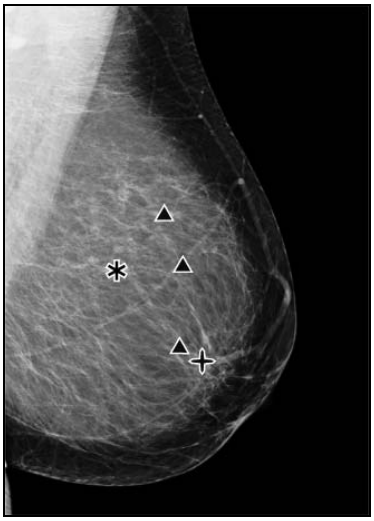
When ImageChecker processes an individual image, it may show a set of CAD marks different from the marks reported when the image is part of a case. The differences are due to the fact that ImageChecker first processes the images individually before analyzing the case. When ImageChecker applies the more sophisticated case processing rules (such as bilateral asymmetry analysis), it may discard marks for regions that are less suspicious. For more information, see '2.3. Image and Case Processing'.

3.3. EmphaSize Marks

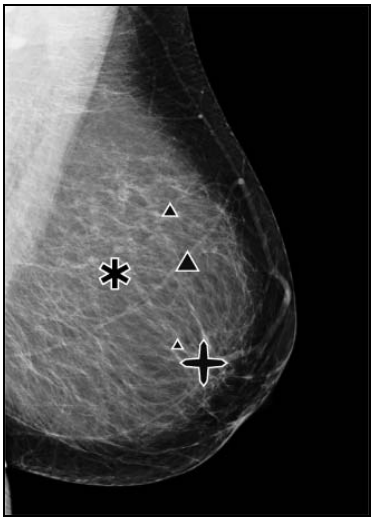
EmphaSize is an optional feature that provides variable-size CAD marks that scale according to feature significance. When the ImageChecker algorithm considers a region to be more significant, it increases the size of the EmphaSize CAD mark. The size of the mark does not correlate to the size of the lesion.

As the algorithm evaluates regions of interest, each region is given a ranking. This ranking along with the selected algorithm operating point determines whether or not the region of interest is marked with a CAD mark.

The system normally displays all CAD marks at the same size regardless of ranking. If your site has enabled the EmphaSize feature and configured the review workstation to use it, the ImageChecker algorithm adjusts the size of each mark according to its ranking. The EmphaSize feature can be disabled if you do not want to use it.



CAD without EmphaSize



CAD with EmphaSize

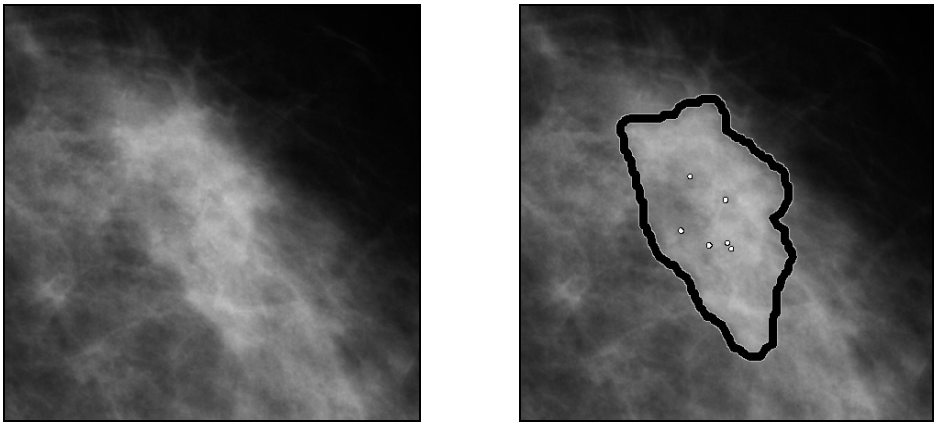
- **Calcifications:** The size of a suspected lesion is of variable significance, since small lesions may be highly significant and large lesions may be nonactionable. However, there are other key characteristics. For calcifications, the algorithm looks at characteristics such as signal intensity, number of calcifications in a cluster, shape of the calcifications (i.e., pleomorphism), and other important features to determine lesion significance.
- **Masses**: For masses, the algorithm looks at characteristics such as degree of spiculation, lesion shape, contrast to surrounding tissue, and other important features which help determine lesion significance.
- **Masses with Calcifications (Malc Marks)**: Regions containing both a mass and calcifications are suspicious and should be carefully evaluated.

⚠ ***Note:*** *Not all mammography workstations can display EmphaSize marks. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

3.4. PeerView and PeerView Digital

PeerView and PeerView Digital are optional licensed features designed to help radiologists better understand why a region of interest was marked. When licensed, PeerView (or PeerView Digital) provides a high-resolution graphical image of the region of interest, which is intended to assist the radiologist in reassessing the mammograms.

- **Calcifications:** PeerView highlights individual calcifications in the cluster marked by the algorithm. PeerView may not highlight all calcifications in a cluster, and it may show features suggestive of calcifications that are not calcifications.
- **Masses:** PeerView defines and outlines the central density of the mass so the radiologist can evaluate the margin, shape, and interior characteristics of the CAD-detected mass or distortion. The outline does not generally include spiculations associated with the mass, although the shape of the central density may lead the eye to larger spicules.
- **Masses with Calcifications:** For composite Malc marks, which indicate that one or more Mass and Calc marks occur at the same location on the image, PeerView highlights the calcifications and outlines the central density of the mass and/or distortion found in the CAD analysis. The same region is shown with and without a PeerView Malc mark (mass with calcifications).



PeerView is licensed on Hologic's CheckMate Ultra display units. When licensed, the CheckMate Ultra accepts the additional high-resolution CAD information from the processing unit (R2 DMax, DM, DX, or LS) so it can be shown on the display unit.

PeerView Digital is licensed on the R2 DMax processing unit. When licensed, PeerView Digital adds graphical information to the Mammography CAD SR output. At the review workstation, the radiologist can use PeerView Digital to highlight regions of interest detected by the ImageChecker algorithm.

⚠ ***Note:*** *Not all mammography workstations can display PeerView Digital highlights. Consult your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

3.5. What the Algorithm Detects

The ImageChecker algorithm searches an image for clusters of bright spots that are suggestive of calcification clusters, for patterns of dense regions, and for dense regions with radiating lines suggestive of masses or architectural distortions.

Calcifications

The algorithm marks:

- Clusters with three or more elements
- Elements that are at or within 3 mm of each other
- Where each element is at least 150 microns in size

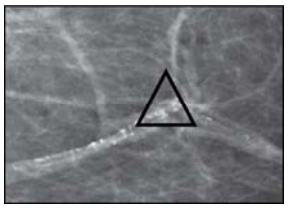
The algorithm does not mark:

- Clusters with fewer than three elements*
- Clusters where each element is separated by more than 3 mm
- Elements it considers to be of benign morphology
- Low-contrast elements
- Lead skin markers or clips

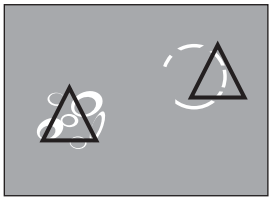
⚠ ***Note:** The algorithm marks two elements if the elements have significant contrast or shape, as defined by the cluster filter. See '**3.6. Detecting Calcifications**'.*

The algorithm occasionally marks:

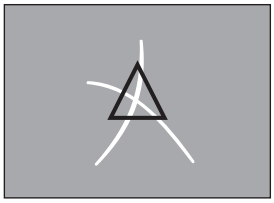
- Calcified arteries
- Cluster or rim benign calcifications
- Crossing linear tissues



Calcified Artery

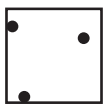


Cluster or Rim
Benign Calcifications

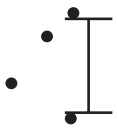


Crossing Linear
Tissues

To be considered a cluster, elements need only be at or within 3 mm of another element within the cluster, as shown next:

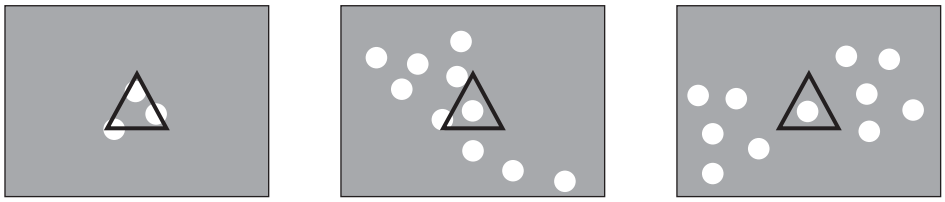


≤ 3 mm square



Each element is
at or within 3 mm

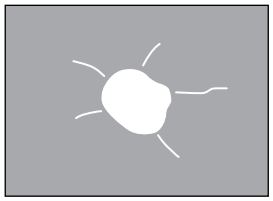
When features in the mammogram meet the ImageChecker criteria, the algorithm places a triangular CAD mark over the center of that region (not over a particular element), as is shown next:



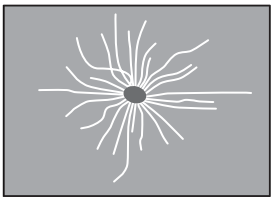
Masses/Architectural Distortions

To detect masses, the ImageChecker algorithm searches the image in a progressive manner looking for circular, dense regions and lines radiating from a common center. The algorithm marks:

- Regions suggestive of masses/architectural distortions
- Dense regions
- Regions with radiating lines



Less pronounced radiating lines but with a central mass

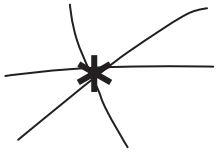


No central mass but pronounced radiating lines

The algorithm occasionally marks:

- Ducts and tissue radiating from the nipple
- Inadvertent crossing of parenchymal tissue
- Well circumscribed masses
- Lymph nodes
- Vague opacities, skin thickening, or nipple retraction

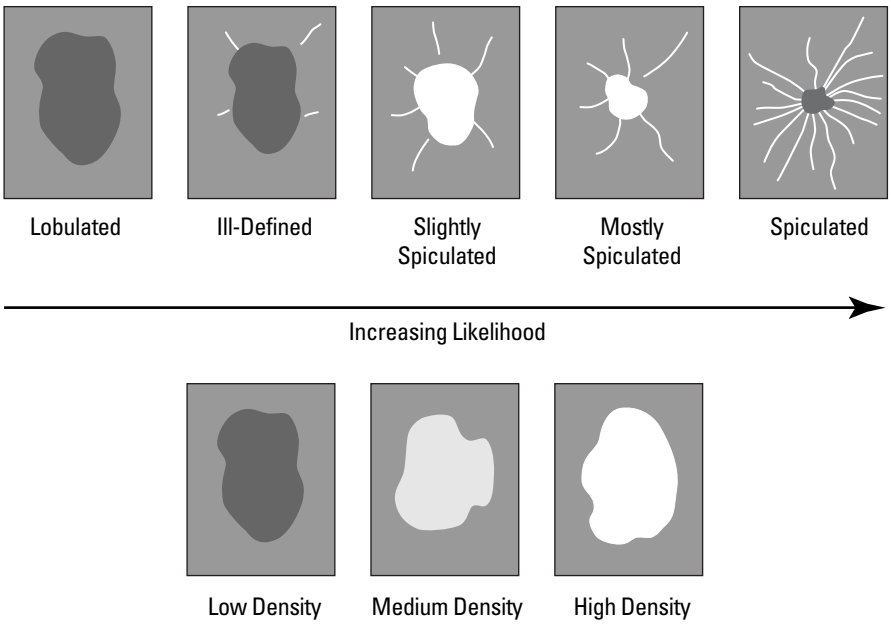
Ducts and tissue radiating from nipple



Inadvertent crossing of parenchymal tissue

The likelihood of a mass/architectural distortion being marked is affected by:

- Margin of the mass (the greater the spiculation, the more likely)
- Degree of density (the higher the density, the more likely)
- Presence of left/right breast asymmetry



When the algorithm finds patterns associated with masses, it places an asterisk at the point of maximum convergence on the image.

3.6. Detecting Calcifications

To detect calcifications, the ImageChecker algorithm performs a series of analyses.

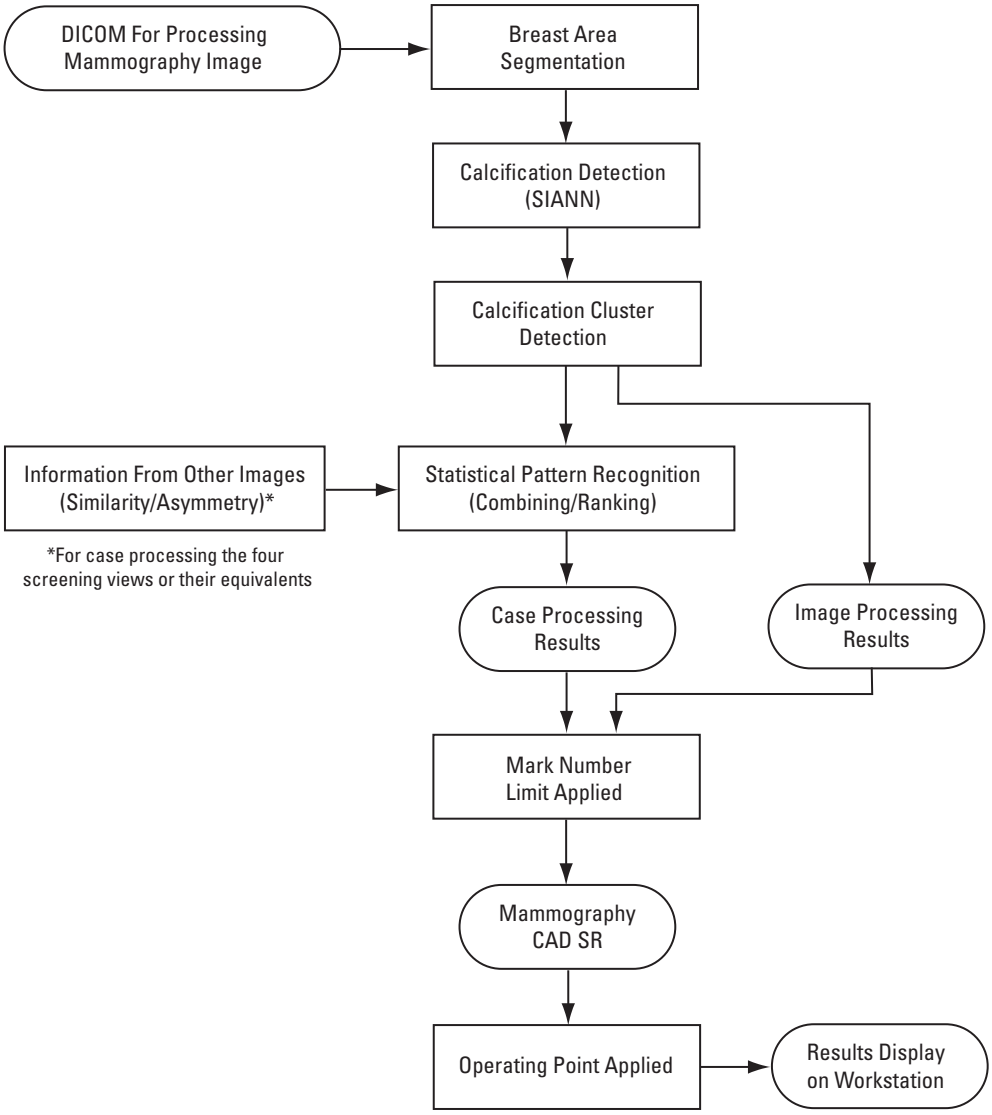
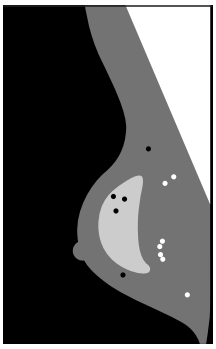


Image Processing for Calcifications



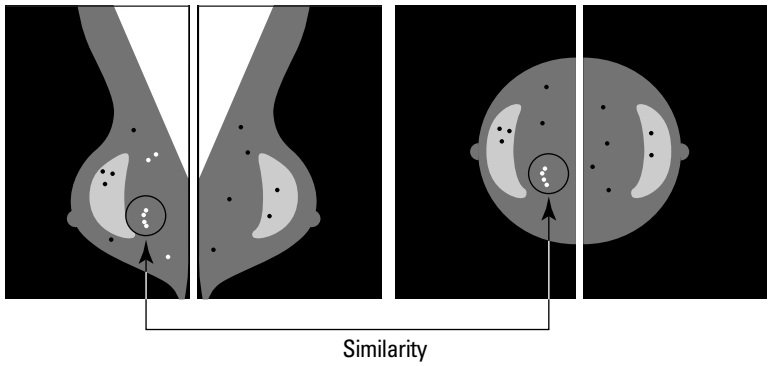
For each image, the algorithm uses two filters (artificial neural networks) to identify calcifications and their features:

- First, it runs each image through a Shift-Invariant Neural Network (SIANN), a calcification detection filter that has been optimized using R2 Technology's large training database. SIANN is a patented technology developed through more than 10 years of research at the University of Chicago.
- Then, it analyzes the resulting calcifications using a cluster filter that weights over a dozen different features, including contrast, shape, and size.

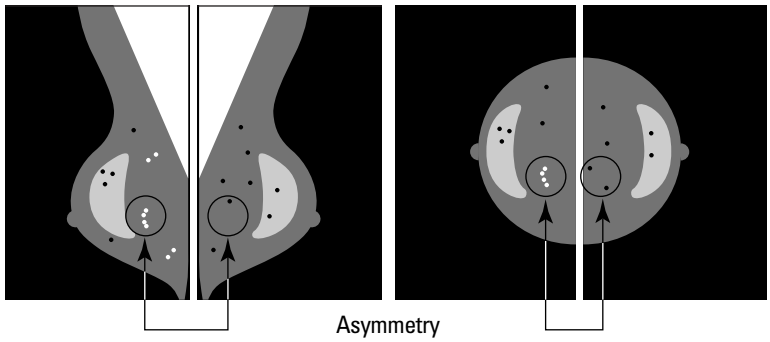
In addition, the algorithm segments the breast and identifies the location of the cluster within the breast.

Case Processing for Calcifications

In addition to processing images individually, the ImageChecker algorithm selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked features.

Finally, if the algorithm determines that a selected Calc mark is coincident with a Mass mark, then the marks are converted into a Malc mark.

For more information see '**2.3. Image and Case Processing**'.

3.7. Detecting Masses

To detect masses, the ImageChecker algorithm performs a series of analyses.

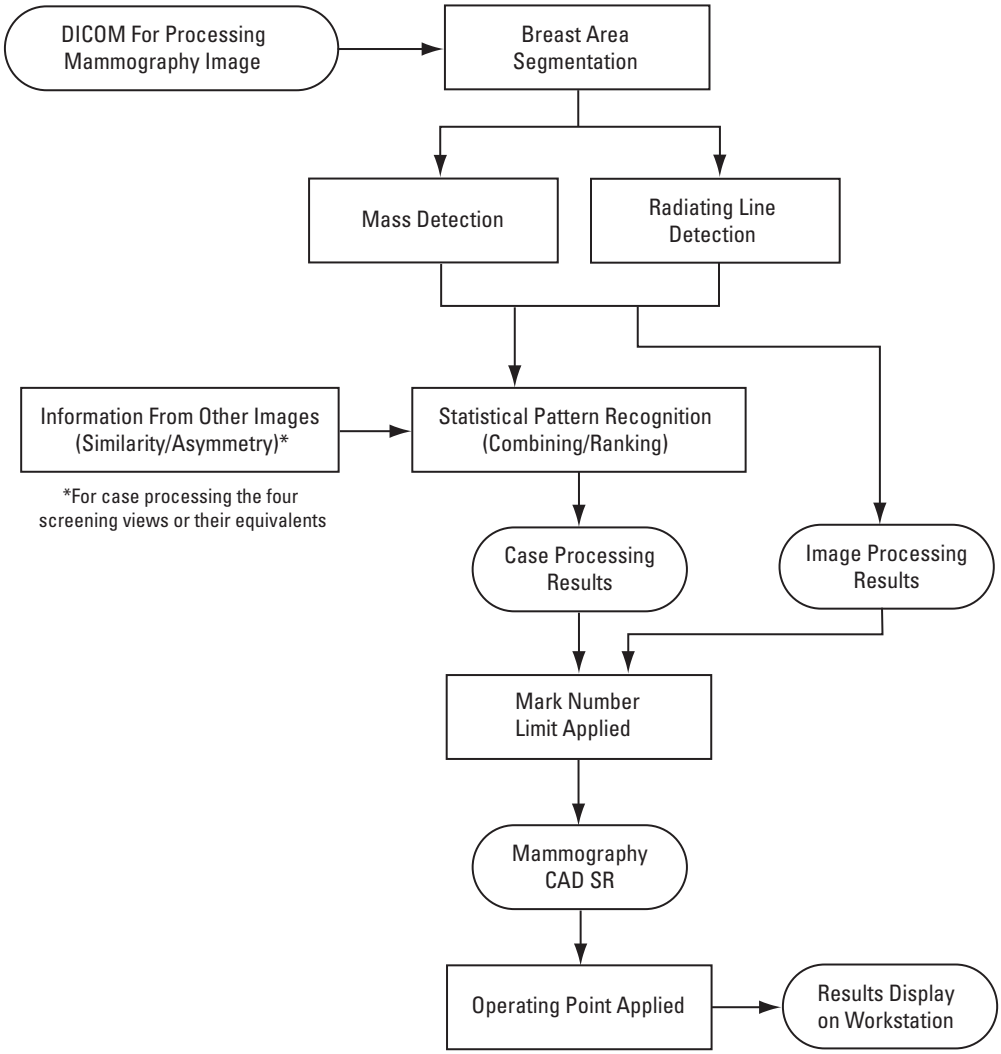
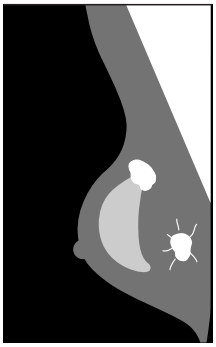


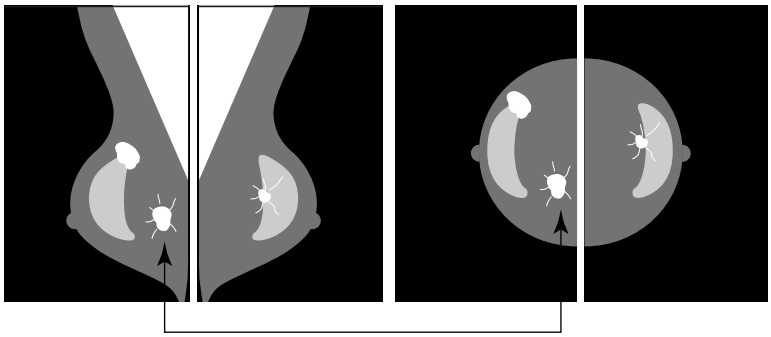
Image Processing for Masses



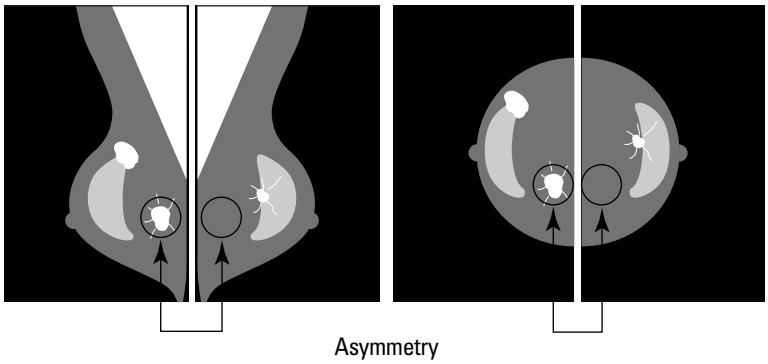
For each image, the algorithm uses patented technology to segment the breast. It then identifies masses by evaluating structures based on their density, shape, and margin characteristics. It also searches for structures appearing as radiating lines, and, if they are present, the degree of spiculation.

Case Processing for Masses

In addition to processing images individually, the ImageChecker algorithm selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



The algorithm then runs the resulting data against the training database to determine the ranking for each of the possible masses. Finally, the algorithm either marks or does not mark the masses, based on the ranking and operating point.

The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked features.

Finally, if the algorithm determines that a selected Mass mark is coincident with a Calc mark, then the marks are converted into a Malc mark.

For more information see '**2.3. Image and Case Processing**'.

3.8. CAD Operating Points

ImageChecker allows each site to choose between three different operating points (i.e., CAD algorithm thresholds). You can choose a different operating point for calcifications than for masses, which provides a total of nine options for operating point combinations. The operating points are summarized below:

- **Operating point 0** trades off a lower false-mark rate for a lower overall sensitivity. This operating point is suited for sites that prefer the system to display the fewest false marks.
- **Operating point 1** represents a balanced intermediate point. Improvements in the algorithm have allowed points 0 and 2 to be set quite far apart, and some sites may want balanced behavior from the CAD algorithm.
- **Operating point 2** focuses on sensitivity. It gives the best performance for marking regions of interest (i.e., CAD sensitivity), with a higher false-mark rate. It is suited for sites that want the system to be as sensitive as possible, regardless of the higher false-positive mark rate.

For example, if you want high sensitivity for calcifications but a moderate balance between sensitivity and false positives for masses, choose operating point 2 for calcifications and operating point 1 for masses.

Each system is shipped with a default set of operating points for both masses and calcifications. You can discuss the choices that are right for your site with your Applications Specialist or, if you would like to change configurations, contact your Hologic Technical Service Representative.

The table below gives the sensitivity and false-mark rate values for the three operating points for ImageChecker software versions 8.5–8.7, as measured on Hologic's large *film* test database of biopsy-proven malignancies and confirmed normal cases for the four screening views (RCC, LCC, RMLO, and LMLO).

Operating Point:	0	1	2
Calcification Cases (n = 588)			
Mean Sensitivity[1]	95%	96%	97%
95% Confidence Interval	93.1–96.7%	94.0–97.2%	95.5–98.3%
Mass Cases (n = 767)			
Mean Sensitivity[1]	83%	88%	90%
95% Confidence Interval	79.8–85.2%	85.6–90.2%	87.7–92.0%
Overall (n = 1355)			
Mean Sensitivity[1]	88%	91%	93%
95% Confidence Interval	86.2–90.0%	89.7–92.7%	91.5–94.3%
False-Positive Marks[2]			
Calcification FP/Image	0.09	0.12	0.16
Mass FP/Image	0.17	0.25	0.35
Total False-Positive Marks/Case	1.0	1.5	2.0
Specificity[2]	48.3%	35.1%	24.5%
95% Confidence Interval	43.7–53.0%	30.6–39.5%	20.5–28.5%

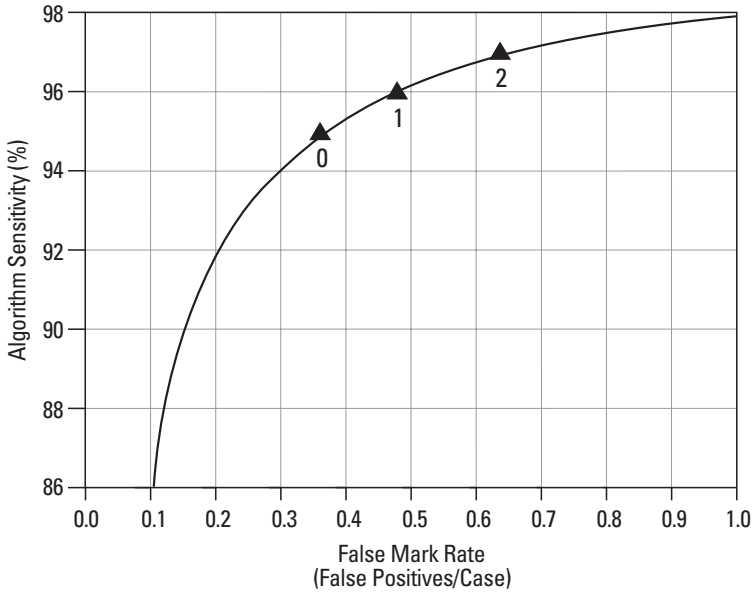
1. 'Sensitivity' refers only to the sensitivity of the CAD algorithm, not to the sensitivity of the radiologist using the device.

2. 'False-Positive' and 'Specificity' data were developed from a review of 445 confirmed normal cases (defined as those with a subsequent normal screening study). 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases. 'Specificity' refers to the percentage of normal cases that, when processed, show no CAD marks.

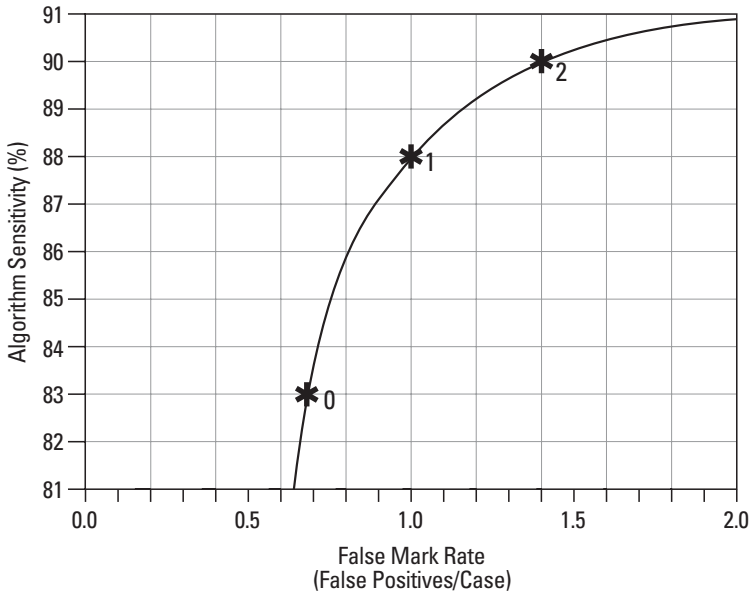
⚠ ***Note:*** *Earlier versions of the ImageChecker algorithm (before version 8.0) produce slightly different performance results. For further information, see the manuals provided with those systems.*

To determine false-mark rates, Hologic processes normal screening cases (defined as those with a subsequent normal screening study) through the ImageChecker software and measures the number of false marks per image. More extraordinary screening cases, such as those with additional views or those from diagnostic studies, may have a very different make-up of images and, as such, may produce results that fall outside the measured normal case mark rate. Since the mark rate is measured per image, a larger number of images in a case should correspond on average with a higher total mark count for that case. While clinical experience demonstrates some variation in mark rates, Hologic has not found the false-mark rate to vary dramatically when averaged over a large number of cases.

The following graphs shows plots of algorithm sensitivity vs. false-mark rate based on cases with the four screening views, with data points for each of the three operating points.



Calcification Performance



Mass Performance

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